

### **REMARKS**

Claims 16-21, 30 and 37 are currently pending in the present application. No claim has been amended in the present response. Further consideration on the merits is respectfully requested.

#### ***Request for Interview***

Applicants kindly request that the Examiner grant an interview to Applicants' representatives before her next action in the present application. Applicants believe that a personal interview in the present application can resolve the outstanding issues and expedite the prosecution of the application.

#### ***Summary of Applicants' Arguments***

Applicants respectfully submit that the data described in the specification and the arguments provided in the previous replies are sufficient to overcome the outstanding rejections of the present claims. Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. "Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). Rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995).

Applicants submit that the previous arguments have established the following:

1. The "active agents" in the present invention and Hidvegi differ because the material used in the present invention contains biomass.

2. Hidvegi does not teach any body weight enhancing effect at all. The immunostimulatory effect claimed therein is supported by metastasis inhibiting data and by data of effects on immune reaction.
3. The claimed range of active agents is not critical, but merely represents a preferred range. It demonstrates that the addition of relatively little amounts of active agent to the fodder enables the enhancement of body weight at a significant rate.
4. The unexpected superiority of the claimed method and claimed effect were demonstrated in many different animals with additional advantages. For example, the additionally advantages include better feed conversion ratio and consequently, less fodder necessity. In the case of turkey fattening, the aorta clefts and deaths resulting therefrom are practically eliminated.

Accordingly, Applicants respectfully request further reconsideration and withdrawal of the outstanding rejections. To facilitate the Examiner's reconsideration of application, Applicants reiterate the arguments from the response on November 19, 2007, below.

***Rejection Under 35 U.S.C. § 103(a), Obviousness***

Claims 16-21, 30 and 37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Hidvegi et al., WO 99/08694 (hereinafter "Hidvegi").

Applicants respectfully traverse.

The Examiner has taken the position that the subject matter of claim 19, i.e. a method of enhancing weight gain and efficiency of feed conversion in a farm animal, is rendered obvious by Hidvegi. The Examiner has alleged that Hidvegi teach a fermented wheat germ extract, as a dried vegetal material and that the dried material can be within the food industry (e.g., a dietary supplement).

However, Applicant respectfully submit that Hidvegi only teach the use of the dried vegetal material as a dietary supplement in form of a mixture with the "usual auxiliary materials applied in food industry, e.g. aromatic materials, sweeteners, coloring agents etc." (see **page 5 line 29 - page 6, line 1**). Hidvegi does not teach that it can be used in general in food industry, as the Examiner suggests, but, only that it can be used together with additives which are generally used in food industry. Claim 10 relates to a mixture consisting of 60% by weight of dried material and 40% by weight of maltodextrin.

A dietary supplement is usually applied to preserve the health and not to enhance the body weight. Based on Hidvegi's teaching, the body weight enhancing effect of dried material is only an assumption of the Examiner, since this effect is neither expressly mentioned nor supported by any data in Hidvegi.

The Examiner has admitted that Hidvegi does not expressly teach adding the fermented wheat germ extract to fodder (to enhance weight gain), as instantly claimed. Moreover, the cited reference teaches that the fermented wheat germ extract is therapeutically useful as an immunostimulatory agent when administered to animals. In essence, the Examiner has equated the immunostimulatory effect and the body weight enhancing effect.

However, Applicants respectfully submit that the Examiner's presumption is erroneous. In Hidvegi, the immunostimulatory effect was indicated in experimental animals such as mice and rats, in all states in which the immune system was damaged (see page 19, lines 2-3 of Hidvegi and Examples). However, Hidvegi does not at all note the effect to enhance body weight of fermented wheat germ extract and its use as a yield-enhancer for healthy farm animals. Applicants note that section V of Hidvegi does mention weight (See Toxicological test, page 18, line 16-28), however Hidvegi discloses that *"the weight of the animals changed like that of the control group"* (emphasis added). This indicates that the dietary supplement disclosed by Hidvegi had no effect on weight gain.

On the contrary, in the present application Applicants proved the weight gain enhancing activity in many different farm animals, such as broiler chicken, hen, roasting goose, feather goose, liver goose, roasting duck, turkey, as well as pig and piglet (see Examples of the present invention). Additionally, this effect is not minimal, but is a significant enhancement.

It should especially be emphasized that there is a great advantage during turkey fattening with respect the aorta cleavages and subsequent deaths which frequently occur due to the rapid growth. Such conditions are practically eliminated as a consequence of the dosage of fermented wheat germ extract of the presently claimed invention. This advantage is surprising in view of the cited prior art.

Therefore, Applicants submit that the effect enhancing weight gain and efficiency of feed conversion was unexpected given the teaching of Hidvegi. As emphasized above, one of ordinary skill in the art at the time of the claimed invention would not have been motivated to add the fermented wheat germ extract to farm animals in order to enhance their weight gain and to improve the efficiency of feed conversion as claimed.

In a previous response, Applicants pointed out the new and advantageous properties provided to by the biomass. See the Office Action dated December 7, 2006 (hereinafter "Previous Response"). Additionally, Applicants wish to point out that the expression "the filtered fermented liquid contained practically no cells" mentioned by the Examiner is only the first fraction of the used product. The addition of the second component, i.e. biomass with cells, provides better and new properties to the extract as we discussed in our previous response (see page 17, third paragraph). The experimental data disclosed in the specification demonstrated the unexpected synergistic activity of the two components of the product used in the instant claimed invention.

Applicants direct the Examiner's attention to the extraordinary advantages of the present invention—namely, that antibiotics can be substituted by the natural substance of the present

invention. This aspect is particularly important given the human consumption of the farm animals (see previous response, page 19, second paragraph).

Applicants additionally direct the Examiner's attention to the comparative experiments by which Applicants have demonstrated that the fermented wheat germ extract used in instant form has *per se* body weight enhancing effect on animals, and it is not solely due to or related to the immunostimulatory effect (See previous response page 19, third paragraph to page 20, second paragraph).

The Examiner has taken the position that the claimed effective amount of fermented wheat germ extract is "merely a matter of judicious selection and routine optimization." However, Applicants respectfully submit that the claimed amount of 0.1-6 g per kg fodder, preferably used 3 g per kg fodder in claim 20, is relatively very low amount compared to the resulting effect.

Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

In the present instance, Applicants have demonstrated the criticality and superiority of the claimed invention. Specifically, Applicants have demonstrated (1) significant enhancement of weight gain that is independent of any immunostimulatory effect; (2) synergistic results from using a combination of biomass with yeast cells; and (3) minimizing pathological conditions frequently associated with rapid growth.

For at least these reasons, Applicants submit that the presently claimed invention is patentably distinct from Hidvegi and that the pending application is in condition for allowance. A Notice of Allowance is earnestly solicited.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole, Reg. No. 60,154 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By

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